The Amendment

Claims 1, 8, 11, and 19 have been amended. All amended claims are supported by the application as filed. No new matter was added by this amendment.

Claim 1 and 19 have been amended to specify that the "plant" is a "cotton plant". Support for this amendment is replete throughout the specification and can be found, for example, on page 19, lines 21-22. Claims 1 and 11 have been amended to specify that the MYB transcription factor is a cotton MYB transcription factor. Support for this limitation is replete throughout the specification and can be found, for example, in the Examples.

Claim 8 has been amended to correct the dependency of the claim in light of canceled claim 7. Claim 8 now depends on claim 1.

Rejections under 35 U.S.C. §112

Claims 1, 3, 5, 7-11, 15 and 17-20 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

The Examiner concedes that the specification is enabling for claims limited to an isolated *Gossypium hirsutum* cDNA GhMYB1 of SEQ ID NO:1 encoding SEQ ID NO:2 and *Arabidopsis* and tobacco plants transform comprising these sequences, but maintains that one of skill in the art would not be able to identify transcription factors within the scope of the claims that would modify transcription in transgenic plants in the same manner as the exemplified sequences. The Examiner contends that it would still require undue experimentation to make and/or use the claimed invention. The rejection is respectfully traversed.

To the extent that the rejection applies to the claims as amended, Applicant respectfully disagrees with the Examiner's assessment. Applicant now claims a method of modulating transcription in a *cotton* plant comprising introducing into the *cotton* plant a recombinant expression cassette comprising a promoter sequence operably linked to a polynucleotide sequence encoding a *cotton* MYB polypeptide, wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1. As

explained during the interview and in the previous amendment, the present specification teaches the highly conserved structural similarities between the claimed cotton MYB transcription factors and other known plant MYB transcription factors from different species. The specification also teaches a method of determining whether a plant was transformed with a MYB nucleic acid by determining fiber qualities. Accordingly, the teachings of the specification, in combination with the level of skill in the art, enable the skilled practitioner to identify MYB nucleic acids of the present invention and to express them in transgenic cotton plants. In the interest of prosecution efficiency, the attached declaration under 37 C.F.R. §1.132 by the inventor, Dr. Thea Wilkins, further underscores the teachings of the specification.

The Examiner states on page 4 of the office action that aside from characteristic domains, the MYB transcription factors of the invention will possess other domains or sequence motifs that allow it to function in its characteristic way. The Examiner then asserts that, given the fact that Applicant has not identified the other regions or other amino acids that are required for the proper function of the cotton fiber MYB transcription factors, one would not be able to identify by sequence alone transcription factors that produce the expected result or any result in regards to modifying transcription. In response, Applicant refers the Examiner to the attached declaration. There, Dr. Wilkins provides evidence of orthologous gene sequences and evidence for phenotypic changes in cotton plant as a result of MYB transcriptional modulation.

A. Identification of Orthologous Gene Sequences for GhMYB1

First, an ortholog to GhMYB1 (*Gossypium hirsutum)* was isolated from *Gossypium arboretum*, *i.e.*, GaMYB1. Sequence alignment of GhMYB1 and GaMYB1 shows a 98% amino acid match in the highly conserved DNA-Binding-Domain of the two polypeptides (see Wilkins Declaration, Exhibit 2). In the declaration (page 2), Dr. Wilkins explains that the critical region spanning the amino-terminal DNA-Binding-Domain (DBD) is conserved among all six cotton GhMYBs. Amino acid identities range from a low of 54.8% (GhMYB5 vs. GhMYB6) to a high of 84.6% (GhMYB1 vs.

GhMYB6). As explained by Dr Wilkins, 98% sequence identity between the GhMYB1 gene and the *Gossypium arboretum* gene indicates that the genes are orthologs. From this evidence, it is clear, that it would require merely routine experimentation, if any, to identify MYB1 transcription factors within the scope of the claims.

B. Phenotypic Changes in Cotton Plant as Evidence for Modulation of Transcription by MYB Proteins

Second, evidence for phenotypic changes in cotton plant as a result of MYB transcriptional modulation is submitted in the declaration (see pages 3-5 of the Wilkins Declaration). Dr. Wilkins provides evidence that changes in GhMYB1 gene expression lead to modified transcription in a cotton plant. Specifically, fiber data were collected from a subset of kanamycin-resistant transgenic cotton plants that contained the transgene for GhMYB1 under the control of the 35S CaMV promoter. Fiber yield (and weight) per seed was found to increase in each of the kanamycin-resistant plants relative to regenerated control plants. In addition, some transgenic plants showed shifts in fiber quality such as fineness and micronaire. In fact, seven out of seven transgenic plants (*i.e.*, plants that express the MYB transgene) analyzed to date showed altered fiber yield, altered fiber weight and/or altered fiber quality. Thus, the function of a cotton fiber MYB1 protein has been shown to include a biological role as a molecular determinant of agronomic properties.

In light of the foregoing amendment and remarks, Applicant respectfully requests withdrawal of the rejection of claims 1, 3, 5, 7-11, 15 and 17-20 under 35 U.S.C. §112, first paragraph.

Claims 1, 7-11 and 17-20 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventor had possession of the claimed invention.

Here, the Examiner's rejection appears to be two-fold. The Examiner asserts that the Applicant does not identify *structural* features unique to the cotton GhMYB1 protein nor the *functional* domains of the protein. The Examiner contends that it remains unclear what features identify a cotton MYB1 protein, including a cotton MYB1 gene with 80% homology to SEQ ID NO:1. The rejection is respectfully traversed.

As shown above, Applicant has clearly established structure and function of a cotton MYB1 (SEQ ID NO: 1). In addition, applicants have identified a second cotton MYB1 gene with 80% homology to SEQ ID NO:1 as shown in the attached declaration of Dr. Wilkins.

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to ***recognize*** that he or she invented what is claimed."[1] Even in *University of California v. Eli Lilly & Co.*, the Court of Appeals for the Federal Circuit stated that a written description for a chemical genus "requires a precise definition, such as by ***structure***, formula, chemical name ***or physical properties***."[2] (Emphasis added).

Since Applicant has described both, the structure and function of a cotton transcription factor MYB1, including a second cotton MYB1 gene with 80% homology to SEQ ID NO:1, the skilled artisan would have no difficulty ***recognizing*** what is claimed. With respect to ***structure***, the declaration describes the identification and characterization of cotton MYB transcription factors (*i.e.*, GhMYB1 and GaMYB1), including one at least 80% identical to SEQ ID NO:1 (*i.e.*, GaMYB1) (see page 2 of the declaration). With respect to ***physical properties***, the declaration describes fiber properties that are regulated by GhMYB1, including fiber yield and weight, fiber fineness, and micronaire (see pages 3-5 of the declaration), thereby providing further evidence for GhMYB1's biological role as a molecular determinant of agronomic

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[1] *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). See also MPEP 2163.02.

[2] *University of California*, 43 USPQ2d at 1405.

properties. In that, the Applicant has complied with the requirement for written description as the declaration further elaborates on what is described in the specification. It is respectfully asserted that the burden now shifts to the Examiner to provide credible reasons or evidence to why one skilled in the art would still not recognize the features that identify a cotton MYB1 protein, including a cotton MYB1 gene with 80% homology to SEQ ID NO:1.

In light of the foregoing amendment and remarks, Applicant respectfully requests withdrawal of the rejection of claims 1, 7-11 and 17-20 under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §103

Claims 1, 3, 5, 9-11, 13, 15 and 18-19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wada *et al.* (1997, Science 277:1113-1116) taken with Wilkins *et al.* (1993, NCBI Accession number L04497).

The Examiner states that the Wada *et al.* reference not only hypothesizes that the CAPRICE (CPC) gene is involved in trichome development, but they demonstrate this fact by over-expressing the CPC gene in *Arabidopsis* which produced plants with ectopic root hairs. The Examiner concludes that, given that root hairs and cotton fibers are related, it would be expected that a transcription factor that affects development of one type of trichome will most likely affect the development of another type of trichome. Furthermore, the Examiner states that the NCBI reference discloses a sequence with MYB domains.

To the extent that the rejection applies to the claims as amended, Applicant respectfully traverses the rejection.

The MPEP states that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a

reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.[3]

Applicants respectfully submit that, in view of the cited publications, one of skill in the art would have had no reasonable expectation of success that the claimed sequences when expressed in plants would modulate transcription in those plants. As the courts have noted, "both the suggestion and the expectation of success must be found in the prior art, not the Applicants' disclosure." *In re Dow Chem. Co.*, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988).

Both references are silent as to the use of cotton MYB1 genes to modulate plant transcription. Furthermore, the Examiner provides no reasoning or evidence to demonstrate that the claimed sequences could be expected to have the phenotypic effect noted here. A skilled practitioner, in view of Wada *et al.* and the NCBI publication, would have no expectation of successfully modulating transcription in a plant by expressing the claimed sequences. In the absence of such a showing the rejection is improper and should be withdrawn.

Moreover, modulation of expression of the claimed genes leads to phenotyptic changes that are different from those reported in the Wada *et al* reference. Wada *et al.* speculate that the CPC gene determines the fate pf epidermal cell differentiation in *Arabiodpsis thaliana* (see page 1113, column 2). They find that the *cpc* mutant has about one-forth the number of root hairs in the primary root compared to the wild type. However, they also find that the morphology and size of the root hairs produced by the *cpc* mutant are indistinguishable from those of wild-type hairs (see page 1113, column 3). As noted above, however, Dr. Wilkins has observed that modulation of the cotton MYB1 genes of the instant invention results in a number of morphological changes. None of these changes were observed with the *cpc* mutant in *A. thaliana*, let alone in cotton.

Finally, the Examiner states on page 4 of the office action that, aside from the characteristic domains, each MYB transcription factor possesses other domains or

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[3] MPEP 2143

sequence motifs that permit it to function in its characteristic way. Thus, as the Examiner acknowledges, MYB transcription factors are not necessarily interchangeable. Applicant respectfully submits that in light of this statement, the Examiner must explain how one of skill could reasonably predict the activity of the claimed genes in the absence of hindsight gleaned from the instant invention.

In light of the foregoing amendment and remarks, Applicant respectfully requests withdrawal of the rejection of claims 1, 3, 5, 9-11, 13, 15 and 18-19 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) A method of modulating transcription in a cotton plant, the method comprising introducing into the cotton plant a recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide sequence encoding a cotton MYB polypeptide, wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1.

8. (Once Amended) The method of claim ~~7~~ 1, wherein the promoter directs expression of the polynucleotide sequence in cotton fibers.

11. (Twice Amended) A recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide sequence encoding a cotton MYB polypeptide, wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1.

19. (Once Amended) A cotton plant comprising the expression cassette of claim 11.